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11 UNITED STATES DISTRICT COURT
12 FOR THE EASTERN DISTRICT OF WASHINGTON
13

14 STATE OF WASHINGTON, *et al.*,

15 Plaintiffs,

16 v.

17 FOOD AND DRUG
18 ADMINISTRATION, *et al.*,

19 Defendants.

No. 1:23-cv-03026

MOTION FOR EXTENSION OF
TIME

03/30/23

WITHOUT ORAL ARGUMENT

20 Pursuant to Local Rule 7, Defendants respectfully request that this Court
21 extend Defendants' time to respond to Plaintiffs' Motion for a Preliminary
22 Injunction by fourteen (14) days, which would result in their response being due on
23 March 24, 2023, instead of March 10, 2023. Counsel for Plaintiffs have informed
24 undersigned counsel that they will oppose this motion.
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1 Good cause exists to grant Defendants' extension request. In support of their
2 82-page Complaint and 35-page Motion for a Preliminary Injunction, Plaintiffs
3 submitted voluminous materials. These include over 400 pages of exhibits attached
4 to their Complaint and nineteen declarations (consisting of over 360 pages) in
5 support of their Motion for a Preliminary Injunction. A two-week extension is
6 necessary to give Defendants sufficient time to carefully review these materials
7 before responding to Plaintiffs' Motion for a Preliminary Injunction.
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10 Such careful consideration is particularly important in this case because of
11 the extraordinary relief that Plaintiffs request. Plaintiffs ask this Court to enjoin the
12 U.S. Food and Drug Administration from enforcing restrictions that FDA has
13 determined are necessary to ensure a drug's safety and effectiveness, and to
14 substitute its judgment for FDA's by concluding that the drug is safe and effective
15 without those restrictions. At a minimum, the Court should ensure that, before
16 ruling on such a request, Defendants have adequate time to review Plaintiffs'
17 lengthy complaint and motion and hundreds of pages of exhibits and declarations.
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20 Moreover, a two-week extension will cause Plaintiffs no prejudice, as
21 evidenced by their extreme delay in seeking a preliminary injunction. In their
22 Motion, Plaintiffs challenge three aspects of the FDA-approved Risk Evaluation
23 and Mitigation Strategy (REMS) for mifepristone for medical termination of early
24 pregnancy. Two of these (the patient agreement form and the provider certification
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27 MOTION FOR EXTENSION OF TIME

1 form) have been in place for the entire time that mifepristone has been approved
2 for this use—*more than twenty-two years*. The third—a certification requirement
3 for pharmacies that dispense mifepristone—was approved on January 3, 2023, at
4 the same time that a *more* restrictive requirement that mifepristone be dispensed in-
5 person in a certified provider’s office was removed. That in-person dispensing
6 requirement—which, like the other two requirements being challenged by
7 Plaintiffs, had been in place since the drug was approved in 2000—prevented *any*
8 pharmacy from dispensing mifepristone for termination of early pregnancy. In
9 other words, for over two decades, distribution of mifepristone has been subject to
10 a set of requirements at least as extensive as the ones Plaintiffs now challenge.
11

12 Finally, Plaintiffs have been on notice that the in-person dispensing
13 requirement would be replaced by a pharmacy certification requirement since
14 December 16, 2021, when FDA announced publicly that the REMS must be
15 modified to remove the in-person dispensing requirement and to permit certified
16 pharmacies to dispense mifepristone.¹ Thus, even assuming that Plaintiffs could
17 not have brought their challenge prior to FDA’s approval of the modified REMS on
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24 ¹ Questions and Answers on Mifepristone for Medical Termination of
25 Pregnancy Through Ten Weeks Gestation, [https://www.fda.gov/drugs/postmarket-](https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=On%20December%2016%2C%202021%2C%20the,in%2Dperso)
26 [n%20dispensing%20requirement%E2%80%9D](https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=On%20December%2016%2C%202021%2C%20the,in%2Dperso) (visited February 28, 2023).

1 January 3, 2023, their delay of nearly two months in seeking relief demonstrates
2 that they will not be prejudiced by a two-week extension.
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4 For the foregoing reasons, Defendants request that the Court grant
5 Defendants a **14-day** extension to respond to Plaintiffs' Motion for Preliminary
6 Injunction, making **March 24, 2023**, Defendants' new deadline.
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9 February 23, 2023

HILARY K. PERKINS
Assistant Director

11 /s/ Noah T. Katzen
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MOTION FOR EXTENSION OF TIME

CERTIFICATE OF SERVICE

I hereby certify that, on February 28, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen
NOAH T. KATZEN

MOTION FOR EXTENSION OF TIME